

File name: Additional file 7

File format: .doc

Title: Round 1 and 2 free text comment summary

Description: A summary of the comments that were provided by participants following both round 1 and 2 of the Delphi survey.

<b>Round 1</b>	<b>Free text comments were summarised by the study team and summary was presented to round 2 participants</b>
	<ul style="list-style-type: none"><li>• Participants said it was important to clearly describe risks in terms of both how often the side effects arose and how serious they were</li><li>• Leaflets should avoid using ‘you’ or ‘your child’ and use more generic ‘some participants’ or ‘some children’.</li><li>• Comparison to known medications can be useful when describing potential harms. For example, saying that the probability of a clot following a vaccine is the same as the probability of a clot linked to smoking or pregnancy.</li><li>• Uncertainty needs to be conveyed (we are usually not sure who will experience a harm).</li><li>• Ways of presenting benefits and harms information will depend on disease area; participant characteristics; clinical trial phase; and risk and intervention complexity)</li><li>• Participants stated that it was important not to over-emphasize trial benefits as these often are unknown.</li><li>• The Drug fact box prompted a number of comments with some participants viewing it as clear, concise and useful as a text breaker and others as confusing and too complicated.</li></ul>
<b>Round 2</b>	<b>Free text comments were summarised by the study team and summary was presented to the consensus meeting participants</b>
	<ul style="list-style-type: none"><li>• Participants mentioned the importance of a balance between severity and frequency (a very rare but very severe side effect should always be listed regardless of frequency).</li><li>• Patient and public input should be mandatory when preparing participant facing trial documentation describing benefits and harms</li><li>• Presented information should take into account the wide range of possible audiences where simple language is complemented with more complex information for example in an appendix or via a weblink (but full and balanced information and clear options for participants should always be offered)</li><li>• It should always be acknowledged that any risk and benefit information is based on existing knowledge and does not necessarily encompass all potential side effects</li><li>• The reversibility of side-effect is important and should be described</li><li>• The use of infographics (as opposed to pictures) might be useful for some but not all participant groups</li></ul>